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(54) Title: MODIFIED RELEASE FORMULATIONS OF AT LEAST ONE FORM OF TRAMADOL

(57) Abstract: The present invention provides for a modified release pharmaceutical composition comprising at least one form of tramadol selected from the group consisting of tramadol, enantiomers thereof, pharmaceutically acceptable salts thereof and combinations thereof, the composition exhibiting an *in vitro* dissolution profile (measured using the USP Basket Method at 75 rpm in 900 ml 0.1 N HCl at 37 °C) such that after 2 hours, from about 0 % up to about 30 % (by weight) of the at least one form of tramadol is released, after 4 hours, from about 5 % to about 22 % (by weight) of the at least one form of tramadol is released, after 6 hours, from about 15 % to about 38 % (by weight) of the at least one form of tramadol is released, after 8 hours, more than about 40 % (by weight) of the at least one form of tramadol is released.

WO 03/072025 A3



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/04866

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 9/22, 9/32, 9/36

US CL :424/468, 470, 480, 482

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/468, 470, 480, 482

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,254,887 B1 (Miller et al) 03 July 2001, see entire document, especially column 4, lines 45-55, column 5, line 63 through column 7, examples 1-8.	1-28

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Further documents are listed in the continuation of Box C.

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See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

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## INTERNATIONAL SEARCH REPORT

International application No.

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### B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

WEST- search terms: tramadol coated tablet, tramadol modified release tablet, dissolution profile or controlled release or sustained release or delayed release, tramadol AUC, Cmax, Cmin, Tmax, tramadol and ethylcellulose or polvinylpyrrolidone or dibutyl sebacate